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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,747	04/13/2001	Hal Sternberg	BIOT008	4271

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)
	09/834,747	STERNBERG, HAL
	Examiner Frank I Choi	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-25 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-25 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other: *Appendix B*

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14,18 indicate that they contain buffer but do not contain a “biological buffer” which renders the claims indefinite as is it uncertain what buffers are and are not included within the scope of the term.

Examiner has duly considered Applicant’s arguments but deems them unpersuasive.

Contrary to Applicant’s assertion, “biological buffer” is not defined by the Specification. Examiner suggests that Applicant insert in the claim the definition set forth in the Specification for “conventional biological buffer”.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative,

under 35 U.S.C. 103(a) as obvious over Taylor et al. (US Pat. 5,514,536) for the reasons of record and the further reasons below.

Taylor et al. expressly discloses a method of administering a blood substitute containing electrolytes, including potassium, sodium, magnesium, calcium, chloride, buffer, including bicarbonate, simple sugar and an oncotic agent, including starch, wherein the subjects are under anesthesia and are hooked up to an oxygenator falling within the scope of applicant's claims (See Examples and Claims). The compositions and/or procedures will cause a reduction in carbon dioxide levels.

Examiner has duly considered Applicant's arguments but deems them unpersuasive. Examiner acknowledges that to anticipate a claim the prior art must contain all the elements and limitation of the claim. However, under current case law, an element or limitation can be inherent in the prior art product or method. See *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Applicant argues that because the prior art solutions may contain hydrogen carbonate and dihydrogen phosphate to combat acidosis that the two part component system is not taught in the prior art. However, Applicant has only shown that the prior art solutions may contain the same to combat acidosis and have not shown that use of an oxygenator will not reduce acidosis. Further, the claims clearly state that the risk of acidosis/acidemia is reduced, as such, the risk is still there. Thus, the optional addition of above buffers is not precluded by the claims. Since the oxygenator will inherently reduce the levels of carbon dioxide, the burden is on Applicant to

show the prior art method or product cannot produce the result, i.e. reduction of the risk of acidosis/acidemia. See *In re King*, 231USPQ 136 (Fed. Cir. 1986); See also *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Further, where the limitation in question is a “means” limitation, the “means” must be found in the Specification. The Specification clearly indicates that oxygenators fall within the scope of the “means” limitation (Specification, pgs. 4, 5). As such, the prior art discloses both the “means” and the “plasma-like” solution.

Finally, Examiner reminds Applicant that in an inherency based rejection under 102/103, the *Graham v. John Deere* factors are not applicable, as such, the arguments relative to obviousness do not appear to overcome the rejection herein.

Claims 1-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Segall et al. (U.S Pat. 5,702,880) or Segall et al. (US Pat. 5,571,801).

Segall et al. expressly discloses a method of administering a blood substitute containing potassium, sodium, magnesium, calcium, chloride, bicarbonate, glucose, Herastarch, wherein the subjects are under anesthesia and are hooked up to an oxygenator falling within the scope of applicant's claims (See Examples and Claims). The compositions and/or procedures will cause a reduction in carbon dioxide levels.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above. With respect to Applicant's arguments concerning the use of bicarbonate, it is noted that like above, the bicarbonate is used if needed. As such, similar to above, the reference to bicarbonate does not show that the prior art product does not reduce

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carbon dioxide levels sufficient to reduce the risk of acidosis/acidemia. Also, the fact that the '880 patent does not discuss acidosis/acidemia is not sufficient to overcome the rejection herein as the reduction in carbon dioxide levels is inherent in the product and method or the prior art. The burden falls on Applicant to show that the prior art product and method cannot produce the same result, i.e. the reduction of carbon dioxide levels sufficient to reduce the risk of acidosis/acidemia.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

November 30, 2002

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600

